REMARKS

1. In response to the Office Action mailed November 17, 2009, Applicants respectfully request reconsideration. Claims 38, 40-46 and 51-53 were last presented for examination, and claims 47 and 48 were withdrawn. In the outstanding Office Action, claims 38, 40-46 and 51-53 were rejected. By the foregoing Amendments, claims 38, 40-48 and 51-53 have been cancelled, and claims 54-82 have been added. Thus, upon entry of this paper, claims 54-82 will be pending in this application. Of these twenty-nine (29) claims, two (2) claims (claims 54 and 70) are independent.

2. Based upon the above Amendments and following Remarks, Applicants respectfully request that all outstanding objections and rejections be reconsidered, and that they be withdrawn.

Priority Claim

3. Applicants thank the Examiner for acknowledging Applicants' claim of foreign priority under 35 U.S.C. §119, and for acknowledging that certified copies of the priority documents have been received.

Drawings

4. The Examiner has failed to indicate whether the drawings have been accepted by the Examiner. Applicants respectfully request that the Examiner indicate in the next official action that the drawings have been accepted by the Examiner.

New Claims

5. As the Examiner is aware, the previously presented claims were subject to an election of species. Claims 38-44 were identified as generic claims, and claims 45-46 were identified as Species C, while claims 47-48 were identified as Species D. The claims of Species C were elected while the claims of Species D were withdrawn.

6. Applicants have added new claims 54-82 to further claim embodiments of the present invention. Applicants submit that claims 54-58, 60-65, 70-76 and 78-81 are generic and that claims 59 and 77 are directed to the subject matter of previously elected Species C. New claims 66-69 and 82 are directed to the subject matter of Species D (i.e., the subject matter of former

claims 47 and 48). As such, Applicants respectfully submit that claims 66-69 and 82 be should be withdrawn from consideration in the next Office Action.

Claim Rejections under §112, Second Paragraph

7. Claims 38, 40-46 and 50-53 have been rejected under 35 U.S.C. 112, second paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner states that "[i]n regards to claims 38 and 52, the Examiner was unable to find support for the combination of elements including the claimed range of 'at least a majority of the circumference of the lead' (i.e., 50-100% of the lead)." (*See*, Office Action, page 2). Applicants have cancelled claims 38 and 52, thereby rendering these rejections moot.

Claim Rejections under §102 over Kramm

8. Claims 38, 40, 42-45, 51 and 52 have been rejected under 35 U.S.C. 102(e) as allegedly being anticipated by U.S. Patent No. 6,936,040 to Kramm et al. (hereinafter, "Kramm"). Applicants have cancelled these claims, thereby rendering these rejections moot.

Claim Rejections under §102 and §103 in view of Kuzma '410

9. Claims 38, 40, 44, 45 and 51 have been rejected under 35 U.S.C. 102(e) as allegedly being anticipated by U.S. Patent No. 6,309,410 to Kuzma et al. (hereinafter, "Kuzma '410"), or under 35 U.S.C. 103(a) as allegedly being unpatentable over Kuzma '410 in view of U.S. Patent No. 6,321,125 to Kuzma (hereinafter, "Kuzma '125"). Applicants have cancelled these claims, thereby rendering these rejections moot.

New Claim 54

10. Applicants' new claim 54 recites, in part, "[a] cochlear implant comprising: . . . an electrode assembly comprising a lead extending from the stimulator unit, and an elongate member having its proximal end contiguous with a distal end of the lead, and wherein the elongate member is implantable in a recipient's cochlea; and . . . an annular collar slidably mounted around the lead such the lead extends through a lumen in the collar, the collar having a chamber therein configured to receive a bioactive substance and an outlet through which the bioactive substance can pass from the chamber to a target site in the recipient." (*See*, Applicants' claim 54, above). For the Examiner's benefit, and without addressing the propriety

of the Examiner's combination of Kuzma '410 and Kuzma '125, Applicants will briefly explain why Applicants' claim 54 is patentable over the art of record.

Kramm

11. Kramm discloses "a method and apparatus for positioning and fixating an electrode lead to stimulate and/or sense activity in the heart." (*See*, Kramm, col. 1, lns. 9-10). In one embodiment, Kramm discloses a "guide catheter 40 [that] includes a flexible tubular body 42 having a distal end 44 and a proximal end 46." (*See*, Kramm, col. 5, lns. 32-34). Kramm further discloses that "[a] distributor 48 is mounted on the distal end," and that an "axial lumen 52 of the tubular body 42 provides a passageway for a lead (e.g., an electrical lead) to be directed out of the distal end 44." (*See*, Kramm, col. 5, lns. 34-35 and 37-39).

12. Kramm also describes the difficulty of implanting an endovenous epicardial lead in the left ventricle of the heart due in part to the "tortuous path" through which the lead is implanted. (*See*, Kramm, col. 2, lns. 31-45). Kramm states that "[t]here is a need for improved methods and apparatus for more efficient placement and fixation of endovenous epicardial left ventricular pacing leads within a heart." (*See*, Kramm, col. 2, lns. 52-54). In addition, Kramm states that "the placement of a lead 14 within the coronary sinus 32 and into a cardiac vein 34 [adjacent to the left ventricle 28] may be problematic due to the physical restrictions and the difficulty in fixating the distal end 20 of the lead 14. The various embodiments of the present invention address these issues and are described herein." (*See*, Kramm, col. 5, lns. 17-22 and 10-11). Thus, Applicants submit that the purpose of guide catheter 40 is to guide a lead along a tortuous path through the heart. (*See*, Kramm, col. 5, lns. 6-31).

13. Accordingly, Applicants submit that Kramm's relatively long, tubular guide catheter 40 (*see* FIG. 3 of Kramm), for guiding a lead along a tortuous path through the heart, is not "an ***annular*** collar," as recited in Applicants' claim 54. (Emphasis added). Applicants note that the definition of "annular" provided by the Merriam-Webster Online Dictionary is "of, relating to, or forming ***a ring***." (*See*, http://www.merriam-webster.com/dictionary/annular; emphasis added). Applicants submit that the tubular guide catheter 40 of Kramm does not form a ring. Thus, Applicants submit that the tubular guide catheter of Kramm cannot reasonably be characterized as "an annular delivery collar," as recited in Applicants' claim 54.

14. Section 2111 of the Manual of Patent Examining Procedure (MPEP) explains that "[t]he Patent and Trademark Office ('PTO') determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest **reasonable** construction '**in light of the specification as it would be interpreted by one of ordinary skill in the art**." *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) (citing *In re Am. Acad. Of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364, 70 USPQ2d 1827 (Fed. Cir. 2004)) (emphasis added). Additionally, "[c]laims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their 'broadest reasonable interpretation'." *In re Marosi,* 710 F.2d 799, 218 USPQ 289, 292 (Fed. Cir. 1983) (quoting *In re Okuzawa,* 537 F.2d 545, 548, 190 USPQ 464, 466 (CCPA 1976)) (emphasis in original).

15. Applicants submit that the tubular guide catheter 40 of Kramm could only be characterized as "an annular collar," as recited in Applicants' claim 54, through an unreasonably broad reading of Applicants' claim 54. Accordingly, Applicants submit that Kramm does not anticipate Applicants' claim 54.

16. Similarly, "[i]n the absence of an express intent to impart a novel meaning to the claim terms, the words are presumed to take on the **ordinary and customary meanings attributed to them by those of ordinary skill in the art**." (*See*, MPEP § 2111.01, quoting *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298, 67 USPQ2d 1132, 1136 (Fed. Cir. 2003) (emphasis added)). "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." (*See,* MPEP § 2111.01, quoting *Phillips,* 415 F.3d 1303, 1313).

17. Applicants submit that the tubular guide catheter 40 of Kramm is not "annular" in accordance with the ordinary and customary meaning of the term, as evidenced by the definition quoted above.

18. For at least the reasons set forth above, Applicants submit that Applicants' claim 54 is allowable over Kramm.

Kuzma '410 and Kuzma '125

19. As noted above, Applicants' new claim 54 recites, in part, "[a] cochlear implant comprising: . . . an annular collar slidably mounted around the lead such the lead extends

through a lumen in the collar, the collar having a chamber therein configured to receive a bioactive substance and an outlet through which the bioactive substance can pass from the chamber to a target site in the recipient." (*See*, Applicants' claim 54, above).

20. Kuzma '410 discloses an electrode array 10 and "an electrode positioner . . . used with the electrode array to press or hold the electrode contacts of the array against the modiolar wall of the cochlea." (*See*, Kuzma '410, col. 5, ln. 63; and col. 3, lines 62-64.) In addition, Kuzma '410 discloses that "[a] drug delivery channel is formed within the body of the electrode array and/or the within the body of the positioner, allowing drugs to be administered through such channel." (*See*, Kuzma '410, col. 3, lines 64-67.) For example, Kuzma '410 illustrates a positioner 20 in FIGS. 2A and 2B, and further illustrates a channel 25' in positioner 20 that may be a drug delivery channel. (*See*, Kuzma '410, col. 6, lines 18-21; and FIGS. 2A and 2B.)

21. Applicants submit that, as illustrated in FIG. 2A of Kuzma '410, positioner 20 and electrode array 10 have similar shapes and dimensions, and extend alongside and curve with one another. Thus, Applicants submit that positioner 20 is not "an annular collar slidably mounted around the lead ***such the lead extends through a lumen in the collar***." (*See*, Applicants' claim 54, above; emphasis added).

22. Similarly, Kuzma '125 discloses an electrode array 10 and various positioners similar to positioner 20 dislcosed in Kuzma '410. However, Applicants submit that Kuzma '125 fails to disclose "an annular collar slidably mounted around the lead ***such the lead extends through a lumen in the collar***," as recited in Applicants' claim 54. (Emphasis added).

23. Accordingly, Applicants submit that neither Kuzma '410 nor Kuzma '125, expressly or inherently disclose all elements of Applicants' claim 54, and that claim 54 is allowable over Kuzma '410 and Kuzma '125.

New Claim 70

24. Applicants new claim 70 is directed to "[a]n implantable tissue stimulating device comprising: an electrode assembly comprising a lead and an elongate member having its proximal end contiguous with a distal end of the lead, and having a one or more electrodes disposed on or in the elongate member; and an annular bioactive substance delivery collar slidably mounted around the lead such the lead extends through a lumen in the collar, the collar having a chamber therein configured to receive a bioactive substance and an outlet through which the bioactive substance can pass from the chamber to a target site in the recipient." (*See*, Applicants' claim 70, above.) For at least the reasons provided above with reference to claim 54, Applicants submit that the cited references fail to disclose the claimed "annular bioactive substance delivery collar." (*See*, Applicants' claim 70, above). Therefore, Applicants submit that claim 70 is patentable over the art of record.

Dependent Claims

25. The dependent claims incorporate all the subject matter of the independent claim and add additional subject matter which makes them independently patentable over the art of record. Accordingly, Applicants respectfully assert that the dependent claims are also allowable over the art of record.

Claims 55 and 71

26. Applicants' claim 55 recites "a stop member, disposed on the electrode assembly, configured to prevent the collar from sliding beyond the stop member toward a distal end of the elongate member." (*See*, Applicants' claim 55, above). As discussed above, Applicants submit that Kramm fails to disclose "an annular collar," as recited in Applicants' claim 54. However, even if the Examiner were to incorrectly characterize guide catheter 40 of Kramm as the annular collar recited in Applicants' claim 54, Applicants submit that Kramm fails to expressly or inherently disclose "a stop member, disposed on the electrode assembly, configured to prevent the collar from sliding beyond the stop member toward a distal end of the elongate member," as recited in Applicants' claim 55.

27. Accordingly, Applicants submit that Applicants' claim 55 is allowable over Kramm for at least this additional reason. Applicants further submit that claim 71, which includes

substantially the same limitations as claim 55, is also patentable over the art of record for at least the additional reasons provided above with reference to claim 55.

Claims 56 and 68

28. Applicants' claim 56 recites "a portion of the lead is configured to be implanted in a middle ear of the recipient, and wherein the collar is dimensioned to move along a portion of the lead implanted in the middle ear." (*See*, Applicants' claim 56, above). As discussed above, Applicants submit that Kramm fails to disclose "an annular collar," as recited in Applicants' claim 54. However, even if the Examiner were to incorrectly characterize guide catheter 40 of Kramm as the annular collar recited in Applicants' claim 54, Applicants submit that Kramm fails to teach or suggest the additional limitations of claim 56.

29. As noted above, Kramm discloses a relatively long, tubular guide catheter 40 for guiding a lead along a tortuous path through the heart. Applicants submit that Kramm fails to disclose or suggest that the guide catheter 40 is dimensioned, not just small enough to fit in the middle ear, but small enough "to slide along a portion of the lead implanted in the middle ear," as recited in Applicants' claim 56. Moreover, Applicants submit that it would not have been obvious to modify guide catheter 40 to have such small dimensions, as such a modification would likely render the guide catheter unsuitable for its intended purpose of directing a lead along a tortuous path to a position adjacent the left ventricle of the heart. (*See*, Kramm, col. 2, lns. 31-54; and col 5, lns. 6-31).

30. Accordingly, Applicants submit that Applicants' claim 56 is allowable over Kramm for at least this additional reason. Applicant further submit that claim 72, which includes substantially the same limitations of claim 56, is also patentable over the art of record for at least these additional reasons provided above with reference to claim 56.

Conclusion

31. In view of the foregoing, this application should be in condition for allowance. A notice to this effect is respectfully requested.

32. Applicants reserve the right to pursue any cancelled claims or other subject matter disclosed in this application in a continuation or divisional application. Any cancellations and amendments of the above claims, therefore, are not to be construed as an admission regarding the patentability of any claims and Applicants reserve the right to pursue such claims in a continuation or divisional application.

Dated: February 17, 2010

Respectfully submitted,

_/Michael G. Verga/_____
Michael G. Verga
Registration No.: 39,410
CONNOLLY BOVE LODGE & HUTZ LLP
1875 Eye Street, NW
Suite 1100
Washington, DC 20006
(202) 331-7111
(202) 293-6229 (Fax)
Attorney for Applicants